

EXHIBIT H

PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of

**CERTAIN INTRAORAL SCANNERS AND
RELATED HARDWARE AND SOFTWARE**

Inv. No. 337-TA-1090

**INITIAL DETERMINATION ON VIOLATION OF SECTION 337;
RECOMMENDED DETERMINATION ON REMEDY AND BONDING**

Administrative Law Judge Dee Lord

(April 26, 2019)

Appearances:

For Complainant Align Technology Inc.:

Blair M. Jacobs, Esq., Christina A. Ondrick, Esq., John S. Holley, Esq., Mark Consilvio, Esq., and Elizabeth Bernard, Esq. of Paul Hastings LLP in Washington, DC; Thomas A. Counts, Esq. and Grant A. Margeson, Esq. of Paul Hastings LLP in San Francisco, CA; and Raymond W. Stockstill, Esq. of Paul Hastings LLP in Costa Mesa, CA.

For Respondents 3Shape A/S, 3Shape Trios A/S, and 3Shape Inc.:

Goutam Patnaik, Esq., Tuhin Ganguly, Esq., and David J. Shaw, Esq. of Pepper Hamilton LLP in Washington, DC; William D. Belanger, Esq., Gregory D. Len, Esq., Frank D. Liu, Esq., Britanee L. Friedman, Esq., and L. Andrew Tseng, Esq. of Pepper Hamilton LLP in Boston, MA, Charles F. Koch of Pepper Hamilton LLP in Redwood City, CA; S. Lloyd Smith, Esq., Kimberly Coghill, Esq., and Kyle Tsui, Esq. of Buchanan Ingersoll & Rooney PC of Alexandria, VA; and Philip L. Hirschhorn, Esq. of Buchanan Ingersoll & Rooney PC of New York, NY.

PUBLIC VERSION

Pursuant to the Notice of Investigation (Dec. 13, 2017) and Commission Rule 210.42, this is the administrative law judge's final initial determination and recommendation determination on remedy and bonding in the matter of *Certain Intraoral Scanners and Related Hardware and Software*, Commission Investigation No. 337-TA-1090. 19 C.F.R. § 210.42(a)(1)(i).

For the reasons discussed herein, it is my final initial determination that there is no violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, and/or the sale within the United States after importation of certain intraoral scanners and related hardware and software with respect to U.S. Patent No. 8,638,447 (the "'447 patent"), U.S. Patent No. 8,638,448 (the "'448 patent"), or U.S. Patent No. 9,615,901 (the "'901 patent").

PUBLIC VERSION

I. BACKGROUND

A. Procedural History

The Commission instituted this investigation in response to a complaint filed by Align Technology, Inc. (“Align”) alleging violations of section 337 of the Tariff Act of 1930, as amended, by reason of infringement of certain claims of U.S. Patent No. 9,615,901 (“the ’901 patent”), U.S. Patent No. 8,638,448 (“the ’448 patent”), U.S. Patent No. 8,638,447 (“the ’447 patent”), U.S. Patent No. 6,845,175 (“the ’175 patent”), and U.S. Patent No. 6,334,853 (“the ’853 patent”) by Respondents 3Shape A/S and 3Shape, Inc. The Commission ordered that an investigation be instituted to determine:

whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain intraoral scanners and related hardware and software by reason of infringement one or more of claims 1-7 and 15-20 of the ’901 patent; claims 1-9 and 15-22 of the ’448 patent; claims 1-7, 10, 12, and 17-24 of the ’447 patent; claims 1-4, 14, 15, and 18-20 of the ’175 patent; and claims 1, 3-7, and 9-13 of the ’853 patent; and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

Notice of Investigation at 2. The investigation was instituted upon publication of the notice of investigation in the *Federal Register* on Tuesday, December 19, 2017. 82 Fed. Reg. 60215-16 (2017); *see* 19 C.F.R. § 210.10(b). 3Shape A/S and 3Shape, Inc. filed a response to the complaint and notice of investigation on January 8, 2018. On March 7, 2018, the complaint and notice of investigation were amended to add 3Shape Trio A/S as a respondent. Order No. 8, *not reviewed by* Comm’n Notice (Mar. 27, 2018). 3Shape A/S, 3Shape, Inc. and 3Shape Trios A/S (collectively, “3Shape”) filed a response to the amended complaint on April 23, 2018.

The investigation was terminated as to the ’853 and ’175 patents and certain claims of the ’447, ’448, and ’901 patents based on the withdrawal of Align’s allegations. Order No. 7 (Mar.

PUBLIC VERSION

6, 2018) (terminating investigation as to the '853 patent), *not reviewed by* Comm'n Notice (Mar. 27, 2018); Order No. 13 (Apr. 19, 2018) (terminating investigation as to claims 4, 15, 18, and 20 of the '175 patent, claims 21 and 22 of the '447 patent, and claims 7 and 20 of the '901 patent), *not reviewed by* Comm'n Notice (May 17, 2018); Order No. 20 (June 2, 2018) (terminating investigation as to claims 2-9 of the '448 patent), *not reviewed by* Comm'n Notice (July 18, 2018); Order No. 20 (Aug. 14, 2018) (terminating investigation as to the '175 patent, claims 1-7, 10, and 12 of the '447 patent, and claim 1 of the '448 patent), *not reviewed by* Comm'n Notice (Aug. 30, 2018); Order No. 34 (terminating claim 18 of the '447 patent and claims 16, 17, 21, and 22 of the '448 patent), *not reviewed by* Comm'n Notice (Nov. 5, 2018).

A *Markman* hearing was held in this investigation on June 20 2018, and a *Markman* order, issued on September 25, 2018. Order No. 28. The evidentiary hearing was held on November 5-9, 2018. The target date is Monday, August 26, 2019. Order No. 45 (Apr. 3, 2019).

B. The Private Parties

1. Complainants

The complainant is Align Technology, Inc. ("Align"). Notice of Investigation at 2. Align is a Delaware corporation with a principal place of business in San Jose, California. Second Amended Complaint ¶ 13. In 2011, Align acquired Cadent Holdings, Inc. ("Cadent"), an Israeli company that owned the patents asserted in this investigation. *Id.* ¶ 15.

2. Respondents

The respondents are 3Shape A/S, 3Shape, Inc. and 3Shape Trios A/S. Order No. 8 (Mar. 7, 2018). 3Shape A/S is a Danish corporation with its principal place of business in Copenhagen, Denmark. Response to Second Amended Complaint ¶ 17. 3Shape, Inc. is a Delaware corporation with a principal place of business in Warren, New Jersey. *Id.* ¶ 18.

PUBLIC VERSION

3Shape Trios A/S is a Danish corporation with its principal place of business in Copenhagen, Denmark. *Id.* ¶ 19. 3Shape A/S, 3Shape, Inc. and 3Shape Trios A/S are “sister” corporations that are wholly-owned subsidiaries of 3Shape Holdings A/S. RIB at 8.

C. Products at Issue

The products at issue are intraoral scanner systems. The accused products are scanners made by 3Shape with the brand name Trios 3, and the domestic industry products are scanners made by Align with the brand name iTero Element.

D. Asserted Patents

Through multiple intervening applications, the '447, '448, and '901 patents claim priority to application PCT/IL 99/004431, filed on August 5, 1999. '447 patent at cover; '448 patent at cover; '901 patent at cover.¹ Because of their common ancestry, the patents' specifications are almost identical. Order No. 32 (Sept. 25, 2018) at 5. All three patents identify the same two individuals as inventors, relate to confocal scanning technology, and are entitled “Method and Apparatus for Imaging Three-Dimensional Structure.” '447 patent at cover; '448 patent at cover; '901 patent at cover. The '447 and '448 patents issued on January 28, 2014 from applications filed on September 14, 2012 and March 4, 2013, respectively. '447 patent at cover; '448 patent at cover. The '901 patent issued on April 11, 2017, from an application filed on June 18, 2015. '901 patent at cover.

1. Patent Specifications

The asserted patents are directed to methods and apparatuses for imaging three-dimensional structures, such as the surface topology of a “teeth segment.” '901 patent, col. 2:28-

¹ The '447 patent is exhibit JX-0001, the '448 patent is exhibit JX-0002, and the '901 patent is JX-0003.

PUBLIC VERSION

X. CONCLUSIONS OF LAW

Based on the foregoing, and the record as a whole, it is my final initial determination that there is no violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, and/or the sale within the United States after importation of certain intraoral scanners and related hardware and software with respect to U.S. Patent No. 8,638,447 (the “’447 patent”), U.S. Patent No. 8,638,448 (the “’448 patent”), or U.S. Patent No. 9,615,901 (the “’901 patent”).

This determination is based on the following conclusions of law:

1. The Commission has subject matter jurisdiction over this investigation, *in personam* jurisdiction over Respondents, and *in rem* jurisdiction over the accused intraoral scanners and related hardware and software.
2. There has been an importation into the United States, sale for importation, or sale within the United States after importation of the accused intraoral scanners and related hardware and software by Respondents.
3. No claims of the ’901 patent have been shown to be infringed by the accused products.
4. No claims of the ’447 patent have been shown to be infringed by the accused products.
5. No claims of the ’448 patent have been shown to be infringed by the accused products.
6. Claim 15 of the ’901 patent is invalid for anticipation. No other claims of the ’901 patent have been shown to be invalid.
7. No claims of the ’447 patent have been shown to be invalid.
8. No claims of the ’448 patent have been shown to be invalid.
9. The domestic industry requirement is satisfied with respect to claims 16-19 of the ’901 patent.
10. The domestic industry requirement has not been satisfied with respect to any claim of the ’447 patent.
11. The domestic industry requirement has not been satisfied with respect to any claim of the ’448 patent.

PUBLIC VERSION

I hereby certify the record in this investigation to the Commission with my final initial determination. Pursuant to Commission Rule 210.38, the record further comprises the Complaint and exhibits thereto filed with the Secretary, the *Markman* order, and the exhibits attached to the parties' summary determination motions and the responses thereto. 19 C.F.R. § 210.38(a).

Pursuant to Commission Rule 210.42(c), this initial determination shall become the determination of the Commission 45 days after the service thereof, unless a party files a petition for review pursuant to Commission Rule 210.43(a), the Commission orders its own review pursuant to Commission Rule 210.44, or the Commission changes the effective date of the initial determination. 19 C.F.R. § 210.42(h)(6).

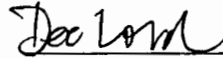
This initial determination is being issued with a confidential designation pursuant to Commission Rule 210.5 and the protective order in this investigation. Within ten (10) days of the date of this initial determination, each party shall submit to the Administrative Law Judge a statement as to whether or not it seeks to have any portion of this document deleted from the public version. *See* 19 C.F.R. § 210.5(f). A party seeking to have a portion of this document deleted from the public version thereof must attach to its submission a copy of the document with red brackets indicating the portion(s) asserted to contain confidential business information.⁴¹ The parties' submissions under this subsection shall not be filed with the Commission Secretary but shall be submitted by paper copy to the Administrative Law Judge

⁴¹ To avoid depriving the public of the basis for understanding the result and reasoning underlying the decision, redactions should be limited. Parties who submit excessive redactions may be required to provide an additional written statement, supported by declarations from individuals with personal knowledge, justifying each proposed redaction and specifically explaining why the information sought to be redacted meets the definition for confidential business information set forth in Commission Rule 201.6(a). 19 C.F.R. § 201.6(a).

PUBLIC VERSION²

and by e-mail to the Administrative Law Judge's attorney advisor.

SO ORDERED.

A handwritten signature in cursive script, appearing to read "Dee Lord", is positioned above a horizontal line.

Dee Lord

Administrative Law Judge

**CERTAIN INTRAORAL SCANNERS AND RELATED
HARDWARE AND SOFTWARE**

Inv. No. 337-TA-1090

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **INITIAL DETERMINATION** has been served to the following parties as indicated, on **May 24, 2019**



Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainants Align Technology, Inc.:

Blair M. Jacobs, Esq.
PAUL HASTINGS, LLP
875 15th Street, NW
Washington, DC 20005

- ☐ Via Hand Delivery
☒ Via Express Delivery
☐ Via First Class Mail
☐ Other: _____

**On Behalf of Respondents 3Shape A/S, 3Shape Trios A/S,
and 3Shape Inc.:**

Goutam Patnaik
PEPPER HAMILTON LLP
Hamilton Square
2000 K Street, NW, Suite 600
Washington, DC 20006

- ☐ Via Hand Delivery
☒ Via Express Delivery
☐ Via First Class Mail
☐ Other: _____